MAQUET
GETINGE GROUP

URGENT-FIELD SAFETY NOTICE
2015-03-31

Please forward this information to all relevant users, biomedical staff in and risk management department concerned in your facility

Subject: Risk of leakage due to accidental displacement of patient cassette

Products affected:

Product	S/N
6677200 FLOW-i C20 6677300 FLOW-i C30 6677400 FLOW-i C40	All serial numbers up to 2753

Dear Valued Customer,

The purpose of this letter is to inform about a potential leakage situation due to an accidental displacement (e.g when switching patient tubings or replacing the CO_2 absorber) of the patient cassette.

There are no reported injuries. It is only a low likelihood that this situation will lead to a clinical dangerous situation.

Our records indicate you have received one or more of these devices. Please inform us of the quantity of units you have and the disposition of units that you no longer have.

Description

MAQUET has discovered that the patient cassette in rare cases accidentally can be displaced e.g when switching patient tubings or replacing the CO_2 absorber.

Indications

If you do a system checkout and the patient cassette is displaced the system checkout will not pass.

If the patient cassette is displaced when the machine is ventilating the leakage can be identified by a large discrepancy between inspired and expired tidal volume. The clinical consequence is stop of ventilation and the notification for the user is the leakage alarm, an

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apnea alarm and an expiratory minute volume low alarm. There is also an indication showing “absorber bypassed” on the screen.

In manual mode, the filling of the bag will be slower and the pressure cannot be kept.

Potential hazards

The leakage can lead to improper ventilation which is a potentially dangerous situation for the patient if not corrected by the user.

Precautions

Always make sure that you set an appropriate minute volume alarm and pay attention to a large difference between inspired and expired tidal volume. Try to avoid excessive forces when switching patient tubings and CO_2 absorber.

If you press the patient cassette back into position, the leakage will stop. This can be done quickly and the anesthesia does not have to be switched off.

Corrective action

A field action is initiated to implement an improved patient cassette latch on affected installed base. This Field Safety Notice is only applicable until the unit has been updated with the improved patient cassette latch.

We apologize for any inconvenience this may cause you and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,

Peter Wedar
Global Product Manager Anesthesia

Lars Berken
Vice President Quality Management

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Document title	Doc-ID
Hardware Update patient cassette locking device	MX-6242

UPDATE INSTRUCTIONS MCC/15/003/IU

PRODUCT: FLOW-I

TITLE: HARDWARE UPDATE PATIENT CASSETTE LOCKING DEVICE

ISSUE DATE: 2015-03-31

UPDATE TYPE: IMMEDIATE

COMPLETION DATE: 2016-03-31

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1 RESPONSIBILITY OF SSU/SSP

1.1 PLANNING

This update is mandatory. The MAQUET Sales & Service Unit (SSU) and the Sales & Service Partner (SSP) are responsible for planning of performance of the update and ordering necessary material in order to fulfill the implementation according to:

- Immediate Update: Promptly, within the specified completion time frame.
- Installed volume list for the SSU/SSP.

1.2 IMPLEMENTATION

The SSU/SSP is responsible for coordinating the customer completion date and placing material orders in a timely manner. The SSU/SSP is responsible for regulating the issuance of update orders to Field Service Engineer (FSE) along with all necessary information.

If a system cannot be updated because:

- it is not affected
- it cannot be located
- the customer refuses the update

this information must be reported by authorized personnel from SSU/SSP to MAQUET Critical Care (MCC).

1.3 REPORTING AND MONITORING

Reporting and monitoring of this update is required and it contains of two parts to be addressed by the SSU/SSP:

1. **Device correction letter** intended for the US market and **Field safety Notice** intended for the rest of the world. The distribution of the Device corrections letter / Field Safety Notice to all concerned customers shall be confirmed to our Quality Department using the Confirmation of Distribution. Refer to below document number for letter device correction letter and Field safety notice.
   - EVU-149158 Device correction letter
   - EVU-149159 Field safety notice.

2. **Update Action**, as described in this Update Instructions, is the actual update to be performed by the FSE:
   - The SSU/SSP is responsible for monitoring the completion date and the number of updates completed.
   - Completion of the update must be reported to MCC via the web application MBase.
     If reporting in MBase is not possible the reporting must be done to Update-Reporting.MCC@maquet.com,
   - There is no need to wait with the reporting until the very last unit has been updated, we appreciate a continuous reporting from you.

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2 UPDATE INFORMATION

2.1 SYSTEMS/PRODUCTS AFFECTED

Affected units, FLOW-i

- All FLOW-i with a serial number up to 2753

2.2 REASON FOR THE UPDATE

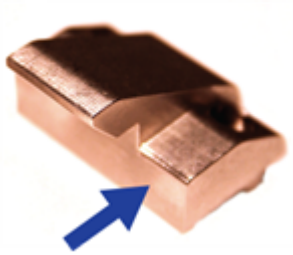
Due to tolerance issues, the patient cassette can get partly disconnected when exposed to external forces, e.g. when the CO2 Absorber is replaced. This is indicated to the user by a leakage alarm. The normal action in a leakage situation is to switch to manual ventilation, but neither manual ventilation nor emergency ventilation works as the leakage is in the breathing circuit. In order to ventilate the patient the leakage must be found and corrected or an external manual bag must be used. A change of the locking device has been implemented to keep the cassette in locked position to prevent potential leakage when the cassettes are subjected to upward forces. The new design was introduced in production of FLOW-i as from S/N 2754.

2.3 PREREQUISITES

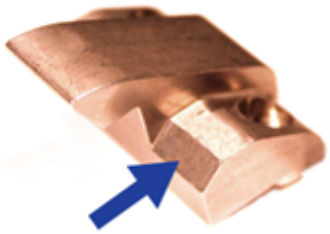
Replacement of the hook (part in the locking device) and the following test is only required if the FLOW-i system is equipped with an old type of hook

It is therefore necessary to verify which existing version of hook is mounted by performing a visual inspection. The new hook has an. 45 ° gradation compared to 90 ° on the old hook

Old = Affected



New = Not Affected



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2.4 SPECIAL TOOLS / DOCUMENTS

- Standard service tools
- Update instruction (this document)
- FLOW-i Service manual
- FLOW-i User's manual

2.5 ORDERING INFORMATION

Place an order as follows for each system to be updated:
Patient cassette hook kit P/N 68 83 732

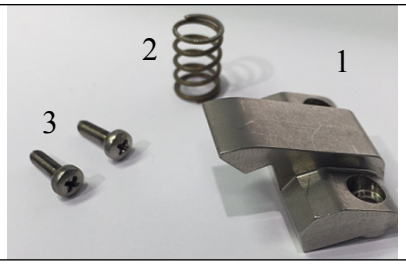
If the test described in section 3.2 fails, the complete locking device must be replaced.
Locking device P/N 66 85 380

List the system Serial Number on FLOW-i on the order!

2.6 CONTENTS OF THE UPDATE KIT

Patient cassette hook kit P/N 68 83 732 contains the following parts

Position	Quantity	Description
1	1	Hook
2	1	Spring
3	2	Screws



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2.7 RETURNS

If the description in section 3.2 fails and the complete locking device is replaced, the replaced locking device must be returned to MCC after completed update, RMA is requested through the MSupport application:

https://mreturn.maquet.com/Home.aspx

1. In MSupport request for an RMA
2. Open “Helpdesk”, chose “create RMA request”
3. Chose category “Other”
4. Under Product Category, chose “Flow-i”
5. Fill in one of the 4 choices of references under reference no
6. Click on “Search”
7. Fill in your own reference ID#
8. In the comment field refer to “MCC/15/003/IU”
9. Add part info, as failure description refer to “MCC/15/003/IU”
10. Check the box “replacement parts ordered”, insert replacement-order references (for correct refund amount)
11. Save request, press get RMA
12. Upon receipt of exchanged “patient cassette locking device” in Solna a credit will be issued

2.8 SPARE PARTS HANDLING

N/A

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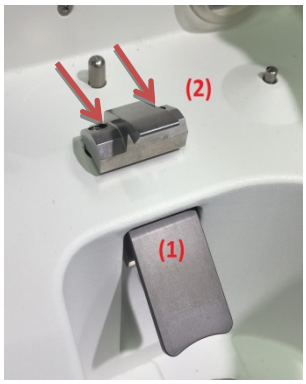
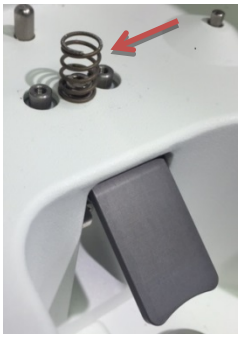
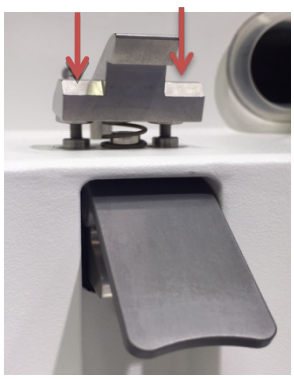
3 UPDATE IMPLEMENTATION

3.1 REPLACEMENT OF THE HOOK

▪ Check that the system is affected. See '2.1 Systems/Products Affected'. ▪ Remove the CO_2 absorber and the patient cassette. ▪ Check that the system has the old version of the hook ▪ Refer to section 2.3 perquisite.	
▪ Open the latch (1) to remove tension on the spring. ▪ Remove the two screws holding the hook (2).	
▪ Replace the spring.	
▪ Mount the new hook using the new screws.	

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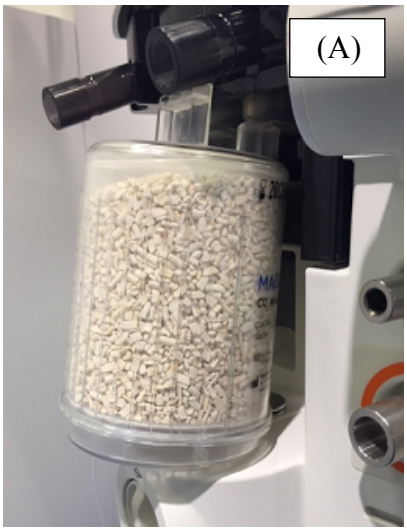
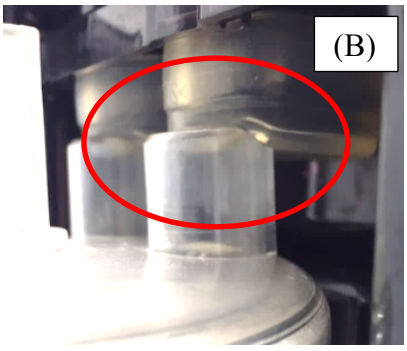
3.2 FUNCTION TEST OF THE NEW HOOK

▪ After the replacement, it is necessary to check the function of the new hook. This is done by performing the following steps:	
▪ Mount the patient cassette and lock it with the latch	
▪ The absorber switch shall be in the unlock position at all time during the test.	
▪ Insert the CO_2 absorber deliberately wrong (A), i.e. let the absorber inlet/outlets push against the silicone seals (B) on the patient cassette.	 

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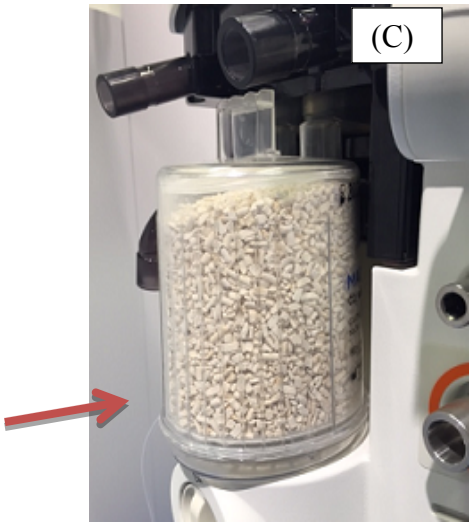
▪ Force the absorber (press inwards) to dock (C). As a result of this the patient cassette will be forced upwards.	
▪ Pull out the CO2 absorber.	
The test passed if: ▪ No click was heard during the test ▪ The patient cassette is still seated in its locked position. ▪ Go to 3.4.	
The test failed if: ▪ A distinct click was heard. ▪ The patient cassette is loose from the locking device. ▪ Go to 3.3.	

3.3 REPLACEMENT OF THE LOCKING DEVICE

▪ Replace the Patient cassette locking device by following the instruction below:	
▪ Open the rear cover of FLOW-i (instruction available in the service manual chapter 'disassembling and assembling').	
▪ Remove the CO_2 absorber and the Patient cassette.	
▪ Remove the hook according to 3.1 - Replacement of the hook.	

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▪ Open the latch and unscrew the screw behind the latch.	
▪ Remove the screw on top of the locking device.	
▪ Remove the locking device by pulling it out from the inside of FLOW-i.	
▪ Mount the new locking device in the reverse order.	
▪ Mount the new hook including the spring using the new screws.	
▪ Close the rear cover.	

3.4 END TEST OF FLOW-I

- Perform a 'System Checkout' to make sure that the system works properly after the update.
  Refer to the 'System Checkout' as described in the User's Manual.
- If applicable, note in the 'Service report' tool, integrated in the Field Service System alt. Service & Settings, that the update is performed (Service key is required).

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3.5 CUSTOMER INFORMATION

Inform the customer of the purpose of this update; refer to '2,2 Reason for the Update'
Also inform the customer that the issue described in the Device correction letter/ Field safety Notice has now been remedied.

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